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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,954	03/19/2004	Marise S. Gottlieb		8077

7590 02/23/2007  
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Suite 300  
1522 "K" Street, N.W.  
Washington, DC 20005

EXAMINER
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CORDERO GARCIA, MARCELA M

ART UNIT	PAPER NUMBER
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1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/804,954	<b>Applicant(s)</b> GOTTLIEB, MARISE S.	
	<b>Examiner</b> Marcela M. Cordero Garcia	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-18 is/are pending in the application.
- 4a) Of the above claim(s) 8-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This Office Action is in response to the reply received on November 22, 2006.

Claims 1-4 and 6-18 are pending in the application. Applicant has now amended claims 1, 3 and 6.

Any rejection from the previous office action, which is not restated here, is withdrawn.

Previously Examiner noted that the species elected by Applicant, namely "YG Product" for treating "obesity associated with the Metabolic Syndrome" was deemed free of the prior art (page 3 of Office Action of August 23, 2006). However, upon reconsideration, Examiner now presents art rejections for "YG Product" for controlling chronic inflammation in an individual having "obesity associated with the Metabolic Syndrome". The search was broadened to encompass "impaired glucose tolerance associated with the Metabolic Syndrome"

Claims 1-4 and 6-7 are presented for examination on the merits. Claims 8-18 are withdrawn as not drawn to the elected Group.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (EP 0230 052 A2) in view of Persselin (Clin Orthop Relat Res, 1991).

Gottlieb teaches a method for controlling rheumatoid arthritis in an individual, comprising administering to said individual an effective dosage of a pharmaceutical composition of YG-Product (e.g., abstract, lines 6-14; page 25, lines 22-29; page 45, lines 1-6). Gottlieb also teaches administering YG-Product with a dermal patch to treat a diabetic, which reads upon an individual having Metabolic Syndrome (see, e.g., page 45, lines 6). Gottlieb does not teach that rheumatoid arthritis is a chronic inflammation disease nor does it teach using elevated levels of C-Reactive Protein, serum fibrinogen, platelet count or platelet activity as markers for chronic inflammation.

Persselin teaches that rheumatoid arthritis necessarily reads upon a chronic systemic inflammatory disease (page 73, column 1, lines 1-3) and that elevated C-reactive protein levels and platelet counts serve as indicators of disease activity (e.g., abstract, lines 20-23).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gottlieb by administering YG-product to a diabetic suffering rheumatoid arthritis using a dermal patch as taught by Gottlieb. The skilled artisan would have been motivated to do so because Gottlieb teaches that YG product may be used to treat rheumatoid arthritis and diabetes (page 25, lines 22-29, page 45, lines 1-6). There would have been a reasonable expectation of success, given that Gottlieb taught that dermal patch administration of YG-product (see, e.g., page 45)

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was faster, required less skill and was less annoying to patients, plus it had a long lasting therapeutic effect, and because Gottlieb taught that YG-product had therapeutic effect over diabetes and over rheumatoid arthritis. Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (EP 0230 052 A2) in view of Persselin (Clin Orthop Relat Res, 1991) in view of L'Italien et al. (US 6,136,784).

Gottlieb and Persselin are relied upon as above. Gottlieb and Perssellin do not teach treating an obese individual.

L'Italient et al teaches that diabetes type 1 is treated commonly with insulin therapy, which is known to cause weight gain as taught by L'Italien et al. (US 6,136,784) [column 6, lines 31-43] and also teaches that many type 2 diabetes patients are often obese (column 2, lines 15-17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gottlieb by administering YG-product to an obese diabetic suffering rheumatoid arthritis. The skilled artisan would have been motivated to do so because Gottlieb teaches that YG product may be used to treat rheumatoid arthritis and diabetes (page 25, lines 22-29, page 45, lines 1-6) and because obesity is present as a side effect or precursor to diabetes as taught by L'Italien. There would have been a reasonable expectation of success, given that

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Gottlieb teaches generically treating diabetes and rheumatoid arthritis using YG-product. Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (EP 0230 052 A2) in view of Persselin (Clin Orthop Relat Res, 1991) in view of Fletcher et al. (JCI, 1952) and in view of Harris (Diabetes Care, 1998).

Gottlieb and Persselin are relied upon as above. Gottlieb and Persselin do not teach the limitations of claim 6, e.g., impaired glucose tolerance or increased fibrinogen.

Harris et al. teach that impaired glucose tolerance is associated to diabetes (e.g., Figures 3; Tables 3-4; page 524, column 1)

Fletcher et al. teach that high levels of fibrinogen are present in rheumatoid arthritis (e.g., page 562, column 1, Results; page 570, column 1 summary).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gottlieb to treat rheumatoid arthritis with high levels of fibrinogen as taught by Fletcher et al. (e.g., Figure 3, Tables 3-4 and page 524) in diabetic patients having impaired glucose tolerance as taught by Harris et al. (e.g., Figures 3; Tables 3-4; page 524, column 1). The skilled artisan would have been motivated to do so because high levels of fibrinogen had been found in rheumatoid arthritis as taught by Fletcher et al. (e.g., Figure 3, Tables 3-4, page 524) and because impaired glucose tolerance was correlated with diabetes as taught by Harris et al. (e.g., Figures 3; Tables 3-4; page 524, column 1). There would have been a reasonable

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expectation of success, given that Gottlieb teaches generically treating diabetes and rheumatoid arthritis using YG-product. Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (US 4,710,380) in view of Gottlieb et al. (US 5,0113,546) and in view of Persselin (Clin Orthop Relat Res, 1991).

Gottlieb US '380 teaches a method for controlling rheumatoid arthritis and diabetes in an individual, comprising administering to said individual an effective dosage of a pharmaceutical composition of containing amplifier Beta (e.g., claims 1, 3-4, 8 and 14).

Gottlieb et al., US '546, teach that amplifier Beta includes Beta 1.11, which is corresponding to YG material (e.g., column 3, lines 38-68 and column 4, lines 1-68 and claims 1-3).

Persselin teaches that rheumatoid arthritis necessarily reads upon a chronic systemic inflammatory disease (page 73, column 1, lines 1-3) and that elevated C-reactive protein levels and platelet counts serve as indicators of disease activity (e.g., abstract, lines 20-23).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gottlieb by administering YG-product to a diabetic suffering rheumatoid arthritis as taught by Gottlieb 'US 380 (e.g., abstract, claims 1, 3-4, 8 and 14). The skilled artisan would have been motivated to do so

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because Gottlieb US '380 teaches amplifier beta (which reads upon YG product according to Gottlieb et al. US '546, e.g., column 3, lines 38-68; column 4, lines 1-68, and claims 1-3) may be used to treat rheumatoid arthritis and diabetes with amplifier Beta (claims 1, 3-4, 8 and 14). There would have been a reasonable expectation of success, given that Gottlieb US '546 teaches that amplifier Beta encompasses YG-product (see, e.g., column 13, lines 33-37 and claims 1-3). Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (US 4,710,380) in view of Gottlieb et al. (US 5,011,546) in view of Persselin (Clin Orthop Relat Res, 1991) and in view of L'Italien et al. (US 6,136,784).

Gottlieb and Persselin are relied upon as above. Gottlieb and Perssellin do not teach treating an obese individual.

L'Italient et al teaches that diabetes type 1 is treated commonly with insulin therapy, which is known to cause weight gain as taught by L'Italien et al. (US 6,136,784) [column 6, lines 31-43] and also teaches that many type 2 diabetes patients are often obese (column 2, lines 15-17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gottlieb by administering YG-product to an *obese* diabetic suffering rheumatoid arthritis. The skilled artisan would have been motivated to do so because Gottlieb teaches that YG product may be used to treat



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rheumatoid arthritis and diabetes (e.g., US '380, claims 1, 3-4, 8 and 14) and because obesity is present as a side effect or precursor to diabetes as taught by L'Italien. There would have been a reasonable expectation of success, given that Gottlieb teaches generically treating diabetes and rheumatoid arthritis using YG-product. Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb (US 4,710,380) in view of Gottlieb et al. (US 5,0113,546) in view of Persselin (Clin Orthop Relat Res, 1991) in view of Fletcher et al. (JCI, 1952) and in view of Harris (Diabetes Care, 1998).

Gottlieb and Persselin are relied upon as above.

Gottlieb and Persselin do not teach the limitations of claim 6, e.g., impaired glucose tolerance or increased fibrinogen.

Harris et al. teach that impaired glucose tolerance is associated to diabetes (e.g., Figures 3; Tables 3-4; page 524, column 1)

Fletcher et al. teach that high levels of fibrinogen are present in rheumatoid arthritis (e.g., page 562, column 1, Results; page 570, column 1 summary).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Gottlieb to treat rheumatoid arthritis with high levels of fibrinogen as taught by Fletcher et al. (e.g., Figure 3, Tables 3-4 and page 524) in diabetic patients having impaired glucose tolerance as taught by Harris et al.

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(e.g., Figures 3; Tables 3-4; page 524, column 1). The skilled artisan would have been motivated to do so because high levels of fibrinogen had been found in rheumatoid arthritis as taught by Fletcher et al. (e.g., Figure 3, Tables 3-4, page 524) and because impaired glucose tolerance was correlated with diabetes as taught by Harris et al. (e.g., Figures 3; Tables 3-4; page 524, column 1). There would have been a reasonable expectation of success, given that Gottlieb teaches generically treating diabetes and rheumatoid arthritis using YG-product (e.g., US '380, claims 1, 3-4, 8 and 14). Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-4 and 6-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8 and 13 of U.S. Patent No. 4,710,380 in view of U.S. Patent No. 5,013,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and US '380 are both drawn to a method for controlling chronic inflammation (e.g., rheumatoid arthritis, claim 4) in an individual having Metabolic Syndrome [such as a diabetic] (claim 8) comprising: administering to said individual an effective dosage of amplifier Beta, which reads upon YG-product as taught by US 5,013,546 (see, e.g., column 13, lines 33-37 and claims 1-3). Further, the instantly claimed method encompasses and/or is encompassed by the claimed method of US '380.

### ***Conclusion***

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Marcela M Cordero Garcia, Ph.D.  
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MMCG 02/07



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